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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/516,381 | 06/10/2005 | Guenther Eissner | 021149-000001 | 4749 |
| 24239 | 7590 | 09/10/2007 | EXAMINER | |
| MOORE & VAN ALLEN PLLC P.O. BOX 13706 Research Triangle Park, NC 27709 | | | BOWMAN, AMY HUDSON | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1635 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/516,381 | EISSNER ET AL. |
| | Examiner | Art Unit |
| | Amy H. Bowman | 1635 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 March 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-5, 7-24 and 26-38 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) _____ is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 1-5, 7-24, and 26-38 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 4, 5, 7-16, 18, 19, 29-33, 36 and 38, drawn to a method of treating a patient undergoing treatment with an immunosuppressant comprising administering a therapeutically effective dose of a protective deoxyribonucleotide and achieving a reduction in complications related to treatment with an immunosuppressant. Election of this group requires further election of one immunosuppressant or one combination of immunosuppressants from claims 4, 5, and 36; as well as either stem cell transplantation, as recited in claims 18 and 19 or bone marrow transplantation, as recited in claim 38, as explained below.

Group II, claim(s) 2, drawn to a method of treating a patient undergoing treatment with an immunosuppressant comprising administering a therapeutically effective dose of a protective deoxyribonucleotide and achieving protection of one or both of the patient's epithelial or endothelial cells from the effects of the immunosuppressant.

Group III, claims 3 and 17, drawn to a method of treating a patient undergoing treatment with an immunosuppressant comprising administering a therapeutically effective dose of a protective deoxyribonucleotide and achieving protection of one or both of the patient's epithelial or endothelial cells from one or both of apoptosis or activation induced by the administration of the immunosuppressant, wherein activation includes enhanced expression of ICAM-1.

Group IV, claims 20-24, 26-28, 34, 35 and 37, drawn to a pharmaceutical composition containing an immunosuppressant and a protective deoxyribonucleotide. Election of this group requires further election of one immunosuppressant or one combination of immunosuppressants from claims 23, 24, and 37, as explained below.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In the instant case, the product is not the first claimed invention and therefore there is no unity of invention between the product and processes. Furthermore, the instant claims do not all fall into one of the only 5 combinations of categories which can have unity of invention as defined by 1.475(b).

Additionally, the technical feature of claim 1 is the administration of a protective deoxyribonucleotide to a subject undergoing treatment with an immunosuppressant and achieving reduction in complications related to treatment with an immunosuppressant, which is not novel in view of the International Search Report filed on 11/30/04 (see X

reference of Sayer et al. (Journal of Cancer Research and Clinical Oncology, vol. 128, no. 3, March 2002, pages 148-152) on page 3 of the International Search Report which teaches successful treatment with an immunosuppressant, methylprednisolone, and defibrotide, wherein defibrotide is recited in instant claim 7). Therefore, there is no special technical feature linking the groups listed above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 4, 5, and 36 of group I, as well as claims 23, 24 and 37 of group IV recite multiple immunosuppressant species. Each of the immunosuppressants is structurally and functionally unique, each requiring a separate and distinct search and corresponding examination. Upon election of group I or IV, applicant is required to elect one immunosuppressant or one specific combination of immunosuppressants from the claims for examination.

Furthermore, claims 18 and 19 recite that the treatment with an immunosuppressant occurs during stem cell transplantation, whereas claim 38 recites that the treatment with an immunosuppressant occurs during bone marrow transplantation. Each of these elements are separate and distinct species, each requiring a separate and distinct search and corresponding examination. Upon election

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of group I, applicant is required to elect either stem cell transplantation or bone marrow transplantation for search and examination.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755. The examiner can normally be reached on Monday-Thursday 6:30 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy H. Bowman/
Patent Examiner
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